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10/525,197	02/22/2005	Nobuhiko Fushimi	Q86306	7757

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EXAMINER	
OLSON, ERIC	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,197	FUSHIMI ET AL.	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-15,18 and 40* is/are allowed.

6)☒ Claim(s) *16,17 and 19-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *February 22, 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This application is a national stage application of PCT/JP03/10551, filed August 21, 2003, which claims priority to foreign applications JP2002-244381, filed August 23, 2002, and JP2002-324076, filed November 7, 2002. Claims 1-40 are pending in this application and examined on the merits herein. Applicant's preliminary amendment submitted February 22, 2005 is acknowledged wherein claims 11-16, 18-22, 24, 25, and 28-39 are amended and the specification is amended to correct minor typographical errors.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-34, 38, and 39 provide for the use of certain pyrazole compounds, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 332-34, 38, and 39 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153

USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions comprising known antidiabetic drugs such as insulin, glyburide, repaglinide, metformin, rosiglitazone, acarbose, and similar drugs, does not reasonably provide enablement for compositions comprising any of the broad classes of second active agents recited in the claims. (e.g. "insulin sensitivity enhancer," "glucose absorption inhibitor," "insulin secretion enhancer," "SGLT2 inhibitor," etc.) The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims;

(6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention is a composition of two or more pharmaceutical active agents. In order to be enabled, one skilled in the art must be able to obtain all of the possible ingredients readily without undue experimentation.

The state of the prior art: Various substances are known to be useful for controlling blood sugar in diabetes, for example insulin, compounds such as sulfonylureas that stimulate insulin production, or compounds such as acarbose that inhibit glucose absorption. Additionally, certain other pharmaceutical agents, such as cholesterol-lowering HMG-CoA inhibitors or blood pressure lowering diuretics, are known to be useful for managing complications of diabetes. However, these classes of drugs are open-ended and defined by functional language. The prior art does not disclose any general method for discovering all possible compounds with a particular activity, (e.g. all compounds that stimulate insulin production) and certainly does not provide a complete, exhaustive list of all such compounds. Also note that the prior art gives no reason to expect all compounds of a given biological function to share a related core structure.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: The diversity of possible chemical substances is very broad, And only a tiny fraction of this diversity has been characterized in the art. Because many different structures can produce the same

function *in vivo*, it is not possible to predict beforehand which compounds will possess a given therapeutic activity.

Furthermore, while many compounds can be produced by chemical synthesis, this process is not completely predictable when applied to every possible compound that one skilled in the art would want to make. The synthesis of a novel organic compound is a complex process involving multiple unpredictable synthetic transformations. Often unforeseen difficulties arise during the synthesis of a novel structure that can only be surmounted by original research and trial and error. Furthermore, the steps necessary to synthesize a compound depend not on its biological function but rather on its structure. Therefore one skilled in the art would find the synthesis of broad classes of structurally unrelated molecules to be highly unpredictable.

The Breadth of the claims: The claimed invention is very broad, including any substance, whether it be an organic small molecule, a polysaccharide, a polypeptide, an oligonucleotide, a viral vector, or any other therapeutic agent that would produce the claimed therapeutic effect.

The amount of direction or guidance presented: Applicant's specification is directed toward certain glycosyloxy-pyrazoles that produce a hypoglycemic effect *in vivo* and are therefore useful for treating diabetes and related conditions. These compounds are shown to work by inhibiting the sodium-dependent glucose cotransporter. While guidance is given for assays that could be used to test novel compounds for SGLT

inhibition, no guidance is given for how to discover antidiabetic compounds that function by any other mechanism, for example by lowering cholesterol.

The presence or absence of working examples: No working examples of any actual therapeutic method are shown.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as the discovery of broad ranges of novel compounds. See MPEP 2164.

The quantity of experimentation necessary: One of ordinary skill in the art, in order to practice the claimed invention with the full range of second therapeutic agents beyond the meager number disclosed in the specification would be required to test potential compounds *in vivo* to determine whether a particular compound is useful in any of the categories claimed. According to the 2006 Chemical Abstracts catalog, (Reference included with PTO-892) The Chemical Abstracts Registry contains entries for approximately 26 million compounds, all of which are potentially included in the claimed invention if they happen to have any of the recited antidiabetic activities. For most compounds, it is unknown whether they are or are not useful as second active agents. Gathering this data for every compound known to man would involve *in vitro* screening of an enormous diversity of chemical compounds for a wide variety of therapeutic activities, as well as *in vivo* testing of compounds having this activity involving either human or animal subjects to determine therapeutic utility. *In vitro* testing requires that the compounds to be tested be synthesized and subjected to an appropriate screening method. As described earlier, synthesis of diverse chemical

structures requires novel and unpredictable experimentation in order to develop suitable synthetic methods. *In vivo* animal experiments include, along with induction of the disease state, administration of the potential pharmaceutical compound and collection and analysis of data, additional burdens associated with compliance with animal welfare regulations, care, feeding, and other maintenance of the animals, dissection of dead animals to collect data, and disposal of dead animals after the protocol is finished. Human tests impose even greater ethical and regulatory burdens, as well as additional difficulty locating subjects. Because of the unpredictability of the art and the lack of comprehensive working examples covering any significant portion of the total number of potential second active agents, these animal experiments would need to be repeated hundreds of times, and involve the maintenance, killing, dissection, and disposal of thousands of experimental animals, to establish the activity or lack thereof of every possible adenosine A_{2A} antagonist, thus presenting an a burden of undue experimentation to anyone practicing the invention with the full range of second agents claimed.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the breadth of the claims and the lack of guidance or working examples, Applicants fail to

provide information sufficient to practice the claimed invention for all of the possible second agents falling within the categories of claims 35-39.

Claims 16, 17, and 19-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds of the general formulae pictured, does not reasonably provide enablement for prodrugs of such compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention is a chemical compound.

The state of the prior art: Some glycosyloxypyrazole compounds are similar structure to the claimed compounds are known in the art. However, prodrugs of these compounds are not known.

Various types of prodrugs exist in the prior art, which are used to produce different active agents *in vivo*. According to Silverman et al., (Reference included with PTO-892) FIND REFERENCE in 11/122251 prodrugs include esters, amides, schiff bases, oximes, acetals, enol esters, redox-activated protecting groups, polymer-bound drugs, bioprecursors, N- or O- alkylated drugs, azo compounds, sulfoxides, disulfides, phosphorylation substrates, and carboxylates, among others.

The relative skill of those in the art: The relative skill in the art is high.

The predictability or unpredictability of the art: As discussed above, there exist many different strategies by which one could attempt to generate a prodrug of a known compound. The appropriate prodrug for a particular application depends on various factors such as the compound being modified, the condition to be treated, the tissue to be affected, the species of the patient, and the desired rate of release. Many different prodrug modifications must be considered to determine the optimal prodrug for each situation.

Furthermore, because the activation of a prodrug depends on its being metabolized *in vivo* by an enzyme, knowledge of the *in vivo* prodrug activity of a compound requires knowledge of the vast array of metabolic enzymes which are capable of acting on it. In order to know every possible prodrug of a compound, one must first know every enzyme which could potentially convert some other compound into that compound. Thus the design of prodrugs is complex and unpredictable.

The Breadth of the claims: The claimed invention encompasses any compound which is metabolized, in whole or in part, into a glycosyloxy-pyrazole compound

according to the instant claims when administered to any living subject, whether plant animal, or other.

The amount of direction or guidance presented: Applicant's specification defines the term "prodrug" in paragraph 231 and furthermore suggests various non-limiting prodrug modifications which could hypothetically be made to the claimed compounds. Applicant's specification does not actually give any guidance beyond this suggestion to try certain compounds.

The presence or absence of working examples: No working examples of prodrugs are provided.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as prodrug design. See MPEP 2164.

The quantity of experimentation necessary: One of ordinary skill in the art, in order to practice the claimed invention with the full range of prodrugs of compounds of formula I, would have to determine which compounds are in fact prodrugs of these active agents. For most derivatives of compounds of formula I, it is unknown whether they are or are not useful as prodrugs. Gathering this data for every compound fitting this description would involve *in vitro* screening of an large diversity of chemical compounds for the desired enzymatic transformation, as well as *in vivo* testing of compound involving either human or animal subjects to determine therapeutic utility. *In vitro* testing requires that the compounds to be tested be synthesized and subjected to an appropriate screening method. Synthesis of diverse chemical structures requires

novel and unpredictable experimentation in order to develop suitable synthetic methods. *In vivo* animal experiments include, along with induction of the disease state, administration of the potential pharmaceutical compound and collection and analysis of data, additional burdens associated with compliance with animal welfare regulations, care, feeding, and other maintenance of the animals, and disposal of dead animals after the protocol is finished. Human tests impose even greater ethical and regulatory burdens, as well as additional difficulty locating subjects. Because of the unpredictability of the art and the lack of comprehensive working examples covering any significant portion of the total number of potential prodrugs, these animal experiments would need to be repeated hundreds of times, and involve the maintenance, killing, dissection, and disposal of thousands of experimental animals, to establish the activity or lack thereof of every potential prodrug, thus presenting an a burden of undue experimentation to anyone practicing the invention with the full range of prodrugs claimed.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the breadth of the claims and the unpredictability of the art, Applicants fail to provide information sufficient to practice the claimed invention for prodrugs of the claimed compounds.

Claims 22, 23, 25, 26, 29, 31, 32, 34, 36, and 38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating certain disorders, does not reasonably provide enablement for preventing those same disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. "Prevention" as discussed herein is interpreted to mean the complete blocking of all symptoms or effects of a disorder for an indefinite period of time.

Nature of the invention: The claimed invention is drawn to a therapeutic method for treatment or prevention of a disorder. Merriam-Webster's Collegiate Dictionary (reference included with PTO-892) defines "prevent" as meaning, "to deprive of power or hope of acting or succeeding," or "to keep from happening or existing." This definition is taken as representing the ordinary usage of the term "preventative". In order to deprive something of power or hope of acting or succeeding, the preventative

agent must be completely effective. "Prevention" as recited in the instant claims, is interpreted to mean the complete and total blocking of all symptoms of a disorder for an indefinite period of time.

The state of the prior art: Certain hypoglycemic agents, including SGLT inhibitors, are known to be useful for treating diabetes. They are not known to be useful as preventative agents in the sense being used herein. In general, prevention of any disorder in the sense being used herein is not a recognized clinical outcome in the art, as no treatment is perfectly effective.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: Prevention of a disease is not the same as treatment of said disease. In order to prevent a disease, as opposed to merely delaying or reducing its symptoms, a treatment must either render the subject completely resistant to said disease after a single treatment or a limited number of treatments, or else, when continued indefinitely, continue to completely suppress the occurrence of said disease. In order to practice a preventative method, one of skill in the art must know the answer to several questions in addition to the effectiveness of the therapy in short-term relief of symptoms, including:

1) What is the duration of a single course of therapy? How often must the therapy be administered to completely suppress the disease?

2) Does the subject develop tolerance to the therapy over time? Does the disease eventually progress to a point where the therapy is unable to completely suppress all symptoms? For example, will a metastatic cancer eventually adapt to

overcome treatments directed to preventing it from metastasizing into the bone? Or will a case of osteoporosis or rheumatoid arthritis ultimately progress to a point where symptoms develop regardless of which therapy is administered.

3) What are the long-term effects of the therapy? Does it cause progressive damage to the kidneys, liver, or other organs? Does the active agent accumulate in the subject's tissues? Is the minimum dose necessary to completely prevent the disease safe for long-term administration? Are there any steps that can be taken to reduce side effects?

For this reason, many therapies which are suitable for short-term relief of symptoms are not suitable for lifelong prevention of disease. For example, antibiotics, chemotherapeutics, and antiviral drugs are not normally administered to healthy subjects in order to prevent the development of infection or cancer.

The Breadth of the claims: In the absence of an explicit definition in Applicant's specification, the claims are given their broadest reasonable interpretation. See MPEP 2111. As described above under the heading "nature of the invention," a preventative effect must include the perfectly effective blocking of any future occurrence of a disease. Merely slowing the onset of disease or making the disease less likely would still leave it with "power or hope of acting or succeeding," and thus not qualify as prevention.

The amount of direction or guidance presented: No guidance is given in the specification suggesting any reason to believe that the claimed compounds are uniquely useful as preventative agents.

The presence or absence of working examples: No working examples are given of any therapeutic methods whatsoever.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as the prevention of disease. See MPEP 2164.

The quantity of experimentation necessary: As mentioned above, the short-term usefulness of a therapy for relief of symptoms is no guarantee of its long-term usefulness for prevention of disease. Because no guidance is given for the use of the claimed therapeutic method for the long-term prevention of disease, one skilled in the art wishing to practice the invention would be unable to do so without first gathering information as to the long-term effectiveness of the therapy. In particular, one skilled in the art, in order to practice the invention for prevention of disease, would need to know whether the preventative effect remains potent over the long term.

In order to answer these questions in the absence of any existing data, one skilled in the art, in order to practice the invention, would undertake long-term animal tests, preferably over a period of years, preferably involving a relatively long-lived experimental animal such as dogs or monkeys, or a human clinical trial. Animal experiments include; along with induction of the disease state, administration of the potential pharmaceutical compound and collection and analysis of data, additional burdens associated with compliance with animal welfare regulations, care, feeding, and other maintenance of the animals, dissection of dead animals to collect data, and disposal of dead animals after the protocol is finished. Administering the claimed

compounds for a period of years to a suitable subject population is an undue amount of experimentation needed in order to practice the full range of the claimed invention. As prevention in the full sense is an extremely high bar for any clinical outcome, there is no reason to believe that the therapy would be successful, and any actual success would be a surprising and unpredictable result.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the breadth of the claims and the nature of the invention, Applicants fail to provide information sufficient to practice the claimed invention for the prevention of diabetes, hypoglycemia, or other disorders.

Conclusion

Claims 16, 17, and 19-39 are rejected. Claims 1-15, 18, and 40 are seen to be allowable over the prior art. Reasons for the indication of allowable subject matter are as follows:

The claimed compounds are seen to be adequately described and enabled by Applicant's specification. For example, pp. 6-43 disclose generic structures and concrete examples showing that Applicant had possession of the claimed invention at the time of filing. Furthermore, the synthetic methods on pp. 45-82 are sufficient to

enable one skilled in the art to make the compounds. P. 85 discusses appropriate methods for using these compounds as therapeutic agents. Pp. 295-298 provide working examples for how to use the compounds to lower blood glucose levels. Therefore the claims meet the requirements of 35 USC 112.

Furthermore, the claimed compounds are seen to be novel and non-obvious over the prior art. Although Applicant has already patented certain other gluocpyranosyloxypyrazole compounds, such as those of US patent 7084123 (Reference cited in PTO-892) these compounds differ from the claimed invention. Specifically, the prior art glycosyloxypyrazoles do not possess the X-Y-N-Z functional group that occurs in all of the claimed compounds. Adding a complex functional group such as this onto a known core structure is not obvious as the prior art gives no indication that this modification would improve the ability of these compounds to inhibit the sodium-dependent glucose cotransporter.

For these reasons the claimed compounds are seen to be allowable over the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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